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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,327

02/24/2004

Paul J. Sheskey

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The Dow Chemical Company
Intellectual Property Section
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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

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04/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/785,327	Applicant(s) SHESKEY ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid particles. The currently pending claims include new claims that are drawn to a nonelected invention, specifically Group III which constituted processes of preparing tablets from granular materials. Therefore claims 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), there being no allowable generic or linking claim.

The claims under examination in this action are 1-8 and 11-16.

Response to Arguments

Applicants' arguments, filed January 31, 2008, have been fully considered but they are moot in view of the new grounds of rejection. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (U.S. Patent No. 4,642,903) in view of Seth et al. (U.S. Patent No. 4,721,709) and the Merck Index.

Davies teaches a method where a solution of water, mannitol, gelatin, and the surfactant sodium lauryl sulfate is combined with the therapeutic Oxazepam (see column 6 lines 26-28 and table III example 15; instant claims 1-4 and 11-12). This composition is taught to contain mannitol and gelatin together at 7.5% of the fluid composition, while the surfactant constitutes 0.27% (as calculated by the examiner – see column 6 lines 26-28 and table III example 15;

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instant claims 1-4, 6, 11-12, and 14). Davies goes on to teach that air bubbles are introduced into the suspension (Oxazepam is practically insoluble in water – see Merck Index record for Oxazepam), thereby contacting the solid particles of therapeutic with the resulting foam (see column 6 lines 28-30; instant claims 1, 2, 7, and 15). Davies also teaches that the gelatin serves a bulk-forming agent and exemplifies other suitable compounds including mannitol and polyethylene glycol which are or are commonly used at a molecular weight of less than 9000 (see column 3 line 64-column 4 line 2; instant claims 5 and 13). It would have been obvious to one of ordinary skill in the art at the time of the invention to use an alternate bulk-forming agent taught by Davies instead of the exemplified gelatin in the method of the invention. Davies does not specifically teach the particle size of the Oxazepam used in the method.

Seth et al. teach a particulate product of Oxazepam whose average diameter is less than 40 μm (see column 5 lines 63-67 and column 8 lines 52-55; instant claims 1 and 2). Further, Seth et al. teach that the particles of their invention can be processed further by any method well known in the pharmaceutical world (see column 8 lines 5-7). Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the particles taught by Seth et al. in the method of Davies. Therefore claims 1-7 and 11-15 are obvious over Davies in view of Seth et al. and the Merck Index.

Claims 1-2, 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies in view of Seth et al. and the Merck Index as applied to claims 1-7 and 11-15 above, and further in view of The Chambers 21st Century Dictionary and the Collins English Dictionary.

Davies in view of Seth et al. and the Merck Index make obvious the method of claims 1 and 2. Davies further teaches that the suspension of therapeutic agent is added dropwise into liquid nitrogen that results in spheres forming (see column 6 lines 34-38; instant claims 8, 16).

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The Collins English Dictionary states that agglomerate means "to form into a mass", thus the forming of drops taught by Davies is interpreted as the formation of one such "mass". Further the Chambers 21st Century Dictionary defines a granule as "a small particle or grain". Davies teaches that the resulting particles of their method measure on average 7.5mm, which is interpreted as a "small particle" (granular material). Thus in view of the definitions provided by the Chambers 21st Century Dictionary and Collins English Dictionary, claims 1-2, 8, and 16 are obvious over Davies in view of Seth et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim requires the same proportion of surfactant as well as the presence of drug in the fluid or solid used in the process as claim 1-2 in patent '828. Both the instant application and patent

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'868 teach a method of contacting particles with foam produced by combining a fluid with gas. In addition, the instant claim requires a range of molecular weights for the surfactant used as well as a range of particle sizes to be coated that each overlap with claims 1-2 of patent '828. Therefore, the claims are not patentably distinct.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit
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